

## **II. RESPONSE TO OFFICE ACTION**

### **A. Status of the Claims**

Claims 1-20, 26-50, 69-77, and 80-89 were pending in the case at the time of the Action, with claims 51-68, 78, and 79 having been withdrawn from consideration as being drawn to a non-elected invention. Claims 1-8, 35, 69-71, and 73-74 have been amended in the Amendment set forth herein. Claims 9-34, 36-68, 72, and 78-90 have been canceled without prejudice or disclaimer. New claims 91-113 have been added. Each of the new claims falls within the scope of the elected Group I invention. Therefore, claims 1-8, 35, 69-71, 73-77, and 91-113 are currently under consideration.

Support for the new claims can be found generally throughout the specification, such as in the following sections of the specification:

Claim 91 – “surface comprises a polymer” – page 2, lines 8-10, and page 6, line 5.

Claim 92 – types of polymers – page 6, lines 5-12

Claim 93 – “surface comprises silicone” – page 6, lines 8-12

Claim 94 – “surface is silk suture” – page 6, lines 8-12.

Examples of support for the remaining new claims and the amendments to the existing claims can be found in the claims as originally filed.

### **B. Teleconference with Examiner**

On September 25, 2006, Applicants’ representatives, Steven Highlander, Monica De La Paz, and client representative Michael Samardzija, conducted a teleconference with Examiner Jastrzab, to discuss the Office Action and a proposed set of amended claims. Agreement was not reached, but Applicants believe that the issues for further prosecution were clarified. Applicants concur with the Interview Summary prepared by the Examiner and dated October 2, 2006.

### **C. The Rejections Under 35 U.S.C. §102 Are Overcome**

#### **1. Rejections Based on Houze *et al.* Are Overcome**

Claims 1-2, 4-5, 12, 14, 28-32, 34, 36-43, 69-71, and 80-82 are rejected under 35 U.S.C. §102(e) as being anticipated by Houze *et al.* Houze *et al.* is said to teach a composition comprising a basic reagent (guanidines, such as alexidine and chlorohexidine) and a dye (gentian violet). Applicants respectfully traverse this rejection and respond as follows.

Without conceding that the claims as originally written were anticipated by Houze *et al.*, Applicants point out that claim 1 is not anticipated because Houze *et al.* fails to disclose any of the dyes set forth in the claim. Further, claims that depend from claim 1 (which include claims 2 and 4-5) are not anticipated. Claims 12, 14, 28-32, 34, 36-43 are no longer at issue in this rejection because they have been canceled without prejudice or disclaimer.

Regarding claim 69, Applicants point out that this claim has been amended to include the limitation set forth in claim 72, a claim that was not rejected. By amending the claim in this manner, Applicants do not concede that the claim as originally written was anticipated by Houze *et al.* Further, claims that depend from claim 69 (*i.e.*, claims 70, 71) are no longer rejected. Claims 80-82 are not at issue because they have been canceled without prejudice or disclaimer.

Further, new claims 91-113 are not anticipated by Houze *et al.* Claims 91-98 depend, either directly or indirectly, from claim 69. Claim 69, as set forth above, is not anticipated. Claims 99 and 101 depend from claim 74, which was not rejected. Claims 100 and 102 depend from claims 99 and 101, respectively, and are therefore not anticipated. Regarding claim 103 and dependent claims 104-108, Houze *et al.* fails to anticipate because it fails to disclose any of the combination of dyes and basic reagents set forth in the claims. Claim 109 and dependent claims 110-111 are not anticipated because Houze *et al.* does not disclose disinfection of a wound. Claim 112 is not anticipated because it depends from claim 1, which for the reasons

discussed above, is not anticipated by Houze *et al.* Claim 113 is not anticipated because Houze *et al.* does not disclose any of the combinations of dyes and basic reagents set forth in the claim.

Therefore, in view of the above, none of the pending claims are anticipated by Houze *et al.*, and the rejection under 35 U.S.C. §102(e) based on Houze *et al.* should be withdrawn.

## **2. Rejections Based on Rosenberg (U.S. Patent 6,465,521)**

Claims 1, 6, 9-10, 12, and 87-89 have been rejected under 35 U.S.C. §102(e) as being anticipated by Rosenberg (U.S. Patent 6,465,521). Applicants respectfully traverse this rejection and respond as follows.

In view of the cancellation of claims 9, 10, 12, and 87-89 without prejudice or disclaimer, the only claims at issue in this rejection include claims 1 and 6.

Regarding claim 1, it is not anticipated because Rosenberg does not set forth any of the dyes now recited in claim 1. Further, claim 6 is not anticipated because it depends from claim 1.

In addition, new claims 91-113 are not anticipated by Rosenberg *et al.* Claims 91, 93-95, and 97 depend from claim 69, which was not rejected. Claims 92, 96, and 98 depend from claims 91, 95, and 97, respectively. Claims 99 and 101 depend from claim 74, which was not rejected as anticipated by Rosenberg. Claims 10 and 102 depend from claims 99 and 101, respectively. Claim 103 is not anticipated by Rosenberg because none of the combination of dyes and basic reagents set forth in this claim are disclosed in Rosenberg. Claims 104-108 depend from claim 103. Claim 109 is not anticipated because Rosenberg does not disclose disinfecting and/or sterilizing a wound. Claims 110-111 depend from claim 109. Claim 112 is not anticipated because it depends from claim 1, which was not rejected as discussed above. Claim 113 is not anticipated by Rosenberg because none of the combinations of dye and basic reagent set forth in this claim are disclosed in Rosenberg.

Therefore, it is respectfully submitted that the rejection of claims 1 and 6 based on Rosenberg should be withdrawn.

### **3. The Rejections Based on Harper Are Overcome**

Claims 1, 8, 12-13, 74, and 80 are rejected under 35 U.S.C. §102(e) as being anticipated by Harper *et al.* In view of the Amendment set forth herein canceling certain claims, the only pending claims at issue in this rejection include claims 1, 8, and 74.

Harper fails to anticipate claims 1, 8, and 74 because it does not disclose any combination of dye and basic reagent set forth in the claim.

Nor are any of the new claims anticipated. Claims 91, 93-95, and 97 depend from claim 69, which was not rejected. Claims 92, 96, and 98 depend from claims 91, 95, and 97, respectively. Claims 99 and 101 depend from claim 74, which was not rejected as anticipated by Rosenberg. Claims 10 and 102 depend from claims 99 and 101, respectively. Claim 103 is not anticipated by Harper because none of the combination of dyes and basic reagents set forth in this claim are disclosed in Harper. Claims 104-108 depend from claim 103. Claim 109 is not anticipated because Harper does not disclose disinfecting and/or sterilizing a wound. Claims 110-111 depend from claim 109. Claim 112 is not anticipated because it depends from claim 1, which was not rejected as discussed above. Claim 113 is not anticipated by Harper because it does not disclose any of the combinations of dye and basic reagent set forth in this claim.

Therefore, it is respectfully submitted that the rejection based on Harper under 35 U.S.C. §102(e) should be withdrawn.

### **4. The Rejections Based on Parikh *et al.* Are Overcome**

Claims 1 and 26-27 are rejected under 35 U.S.C. §102(a) or (e) as being anticipated by Parikh *et al.* Applicants respectfully traverse.

In view of the cancellation of claims 26-27 without prejudice or disclaimer, the only claim at issue in this rejection is claim 1. Claim 1 is not anticipated because Parikh *et al.* fails to expressly or inherently disclose any combination of dye and basic reagent set forth in claim 1.

Further, none of the new claims are anticipated by Parikh *et al.* Claims 91, 93-95, and 97 depend from claim 69, which was not included in this rejection. Claims 92, 96, and 98 depend from claims 91, 95, and 97, respectively. Claims 99 and 101 depend from claim 74, which was not included in this rejection. Claims 10 and 102 depend from claims 99 and 101, respectively. Claim 103 is not anticipated by Parikh *et al.* because none of the combination of dyes and basic reagents set forth in the claim are expressly or inherently disclosed. Claims 104-108 depend from claim 103. Claim 109 is not anticipated because Parikh *et al.* does not disclose disinfecting and/or sterilizing a wound. Claims 110-111 depend from claim 109. Claim 112 is not anticipated because it depends from claim 1, which was not included in this rejection. Claim 113 is not anticipated by Parikh *et al.* because it does not disclose any of the combinations of dye and basic reagent set forth in the claim.

#### **5. The Rejections Based on Zhuang *et al.* Are Overcome**

Claims 1 and 80 are rejected under 35 U.S.C. §102(e) as being anticipated by Zhuang *et al.* Applicants respectfully traverse.

In view of the cancellation of claim 80 without prejudice or disclaimer, the only claim at issue in this rejection is claim 1. Claim 1 is not anticipated by Zhuang *et al.* because no combination of dye and basic reagent set forth in claim 1 is expressly or inherently disclosed in Zhuang *et al.*

Nor are any of new claims 91-113 anticipated by Zhuang *et al.* Claims 91, 93-95, and 97 depend from claim 69, which was not included in this rejection. Claims 92, 96, and 98 depend from claims 91, 95, and 97, respectively. Claims 99 and 101 depend from claim 74, which was

not included in this rejection. Claims 10 and 102 depend from claims 99 and 101, respectively. Claim 103 is not anticipated by Zhuang *et al.* because none of the combination of dyes and basic reagents set forth in the claim are expressly or inherently disclosed. Claims 104-108 depend from claim 103. Claim 109 is not anticipated because Zhuang *et al.* does not disclose disinfecting and/or sterilizing a wound. Claims 110-111 depend from claim 109. Claim 112 is not anticipated because it depends from claim 1, which as discussed above is not anticipated by Zhuang *et al.* Claim 113 is not anticipated by Zhuang *et al.* because it does not disclose any of the combinations of dye and basic reagent set forth in the claim.

**D. The Rejections Under 35 U.S.C. §103(a) Are Overcome**

**1. Rejections Based on Harper *et al.***

Claims 75-77 are rejected under 35 U.S.C. §103(a) as being unpatentable over Harper *et al.*, as applied to claims 1, 8, 12-13, 74, and 80 above. Applicants respectfully traverse this rejection, and respond as follows.

In order to establish a *prima facie* case of obviousness, three basic criteria must be met: (1) the prior art reference (or references when combined) must teach or suggest all the claim limitations; (2) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; (3) there must be a reasonable expectation of success. *Manual of Patent Examining Procedure* § 2142. See also *In re Vaack*, 947 F.2d 488, 20 U.S.P.Q. 2d 1438 (Fed Cir. 1991). It is important to note that all three elements must be shown to establish a *prima facie* case of obviousness. Thus, if one element is missing, a *prima facie* case of obviousness does not exist.

There is no *prima facie* case of obviousness because Harper *et al.* fails to teach or suggest all of the claim limitations. Each of the claims at issue depends from claim 74. Harper *et al.*

does not disclose any of the compositions set forth in claim 74. More particularly, Harper *et al.* does not teach or suggest any combination of a basic reagent and dye as set forth in claim 74. There are a potentially vast number of possible combinations of any basic reagent and any dye; nothing in Harper *et al.* provides any teaching or suggestion to provide for any specific combination of basic reagent and dye set forth in claim 74. Nor has the Examiner cited any teaching or suggestion to provide for the missing limitation. Further, there is no teaching or suggestion in Harper *et al.* to provide for any of the fluids set forth in claims 75-77. Therefore, in the absence of a teaching or suggestion as to each limitation of the claimed invention, there can be no *prima facie* case of obviousness.

**2. Rejections Based on Harper *et al.* and further in view of Kirk-Othmer Encyclopedia of Chemical Technology**

Claims 6, 7, 9, 11, and 15-20 are rejected under 35 U.S.C. §103(a) as being unpatentable over Harper *et al.* as applied to claim 1 above, and further in view of Kirk-Othmer Encyclopedia of Chemical Technology. Applicants respectfully traverse.

In view of the cancellation of claims 9, 11, and 15-20 without prejudice or disclaimer, the only claims at issue in this rejection include claims 6 and 7.

There is no *prima facie* case of obviousness because the combination of Harper *et al.* and Kirk-Othmer Encyclopedia fails to teach or suggest each limitation of the claimed invention. More particularly, as to claim 6, neither reference teaches or suggests triclosan. Further, as to claim 7, neither references teaches or suggests brilliant green. In accordance with *In re Vaeck*, in the absence of any teaching or suggestion as to each limitation of the claimed invention, there can be no *prima facie* case of obviousness. *In re Vaeck*, 947 F.2d 488. Therefore, it is respectfully requested that this rejection should be withdrawn.

### **3. Rejections Based on Houze *et al.***

Claims 3, 33, and 44-50 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Houze *et al.* Applicants respectfully traverse, and respond as follows.

In view of the cancellation of claims 33 and 44-50 without prejudice or disclaimer, the only claim at issue in this rejection is claim 3.

With respect to claim 3, the Action indicates that this claim was rejected in part because of the recitation of ionic bonding. However, Applicants note that claim 3 has been amended to omit reference to ionic bonding. Thus, the rejection appears moot.

Applicants nevertheless note that there can be no *prima facie* case of obviousness because Houze *et al.* does not teach or suggest octenidine or any of the dyes set forth in claim 1, the claim from which claim 3 depends. In the absence of a teaching or suggestion as to each limitation of the claimed invention, there can be no *prima facie* case of obviousness.

### **4. Rejections Based on Rosenberg *et al.* in View of Kirk-Othmer Encyclopedia**

Claims 83-86 are rejected under 35 U.S.C. §103(a) as being unpatentable over Rosenberg *et al.* in view of Kirk-Othmer Encyclopedia. Applicants respectfully traverse.

This rejection is moot because claims 83-86 have been canceled without prejudice or disclaimer.

### **5. New Claims Are Nonobvious In View of Each of the References Cited in the Action**

Each of the new claims is nonobvious in view of each of the references cited under 35 U.S.C. §103(a). Claim 69 was not rejected under 35 U.S.C. §103(a), and new claims 91-98 (which depend from claim 69) are therefore nonobvious. Claims 99-102 depend from claim 74, which was not subject to an obviousness rejection. Claim 103 includes subject matter from original claim 69 (pertaining to an organic surface), and it is noted that claim 69 was not subject

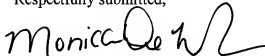


to an obviousness rejection in the present Action. Therefore, claim 103 and dependent claims 104-108 should also be nonobvious. Claims 109-111 are nonobvious in view of each of the references cited under 35 U.S.C. §103(a) because none of the cited reference provide any teaching or suggestion pertaining to a method for disinfecting and/or sterilizing a wound that involves applying a composition that includes gentian violet and a basic reagent to the wound. Claim 112 depends from claim 1, which was not subject to an obviousness rejection in the present Action. New claim 113 pertains to a composition prepared by a process that involve admixing a dye and a basic reagent, wherein the dyes and basic reagents are analogous to those set forth in claim 1. Claim 1 was not subject to an obviousness rejection in this Action. Therefore, it appears to Applicants that the Examiner would consider each of the new claims nonobvious in view of the prior art cited in the rejections under 35 U.S.C. §103(a).

#### **E. Conclusion**

In view of the above, each of the pending claims is believed to be in condition for allowance, and a Notice of Allowance is earnestly solicited. The Examiner is invited to contact the undersigned attorney at (512) 536-5639 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,



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